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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,659	12/17/2001	Steven Arthur Haney	02368/41	2672

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,659	HANEY ET AL.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8* is/are pending in the application.

4a) Of the above claim(s) *5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 7/26/2004 is acknowledged and entered. Claims 6-7 have canceled. Claim 1 has been amended. Claim 8 has been added. Although claim 8 was added in the preliminary amendment filed 1/2/2004, the amendment was not match with the file until after the previous Office Action was mailed, i.e. mailed date of 3/25/2004.

2. Claims 1-5, and 8 are pending.

Election/Restrictions

3. Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to ***a nonelected invention***, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/2/2004.

4. Claims 1-4, and 8 are treated on the merit in this Office Action.

Maintained Rejections

Claim Rejections - 35 USC § 112

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-4 and (new claim) 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

The instant claim 1 recites a method of making an expression library containing a gene that is toxic to bacteria comprising the steps of a) isolating genomic DNA from a first bacterium that is toxic to a second bacterium; b) partially digesting the genomic DNA to produce genetic inserts; c) cloning the genetic inserts into a cloning vector; d) ligating together the genetic inserts and cloning vectors to produce ligation products; e) transforming the ligation products directly into yeast; f) amplifying the ligation products in yeast.

The specification disclosure does not sufficiently teach the method of making an expression library containing a gene that is toxic to bacteria because the claimed method requires prior knowledge that the "gene" in the first bacterium would be toxic to the second bacterium in order to isolate it. The specification description is directed to the method of isolating of genomic DNA (pg. 6, paragraph [0018]) and the examples are drawn to the method of isolating *E. coli* and *B. subtilis* chromosomal DNA (pg. 17, paragraph [0048] and [0049]). Thus the specification is silent on the method of isolating the genomic DNA of the first bacterium that would contain the gene that is toxic to the second bacterium.

The specification disclosure does not sufficiently teach the presently claimed method wherein "one toxic gene" is toxic to ***any*** bacterium. The specification description asserted that the gene is "toxic" to *E. coli* and *B. subtilis* (pg. 5, paragraph [0015], lines 5-7). Thus the

specification clearly does not provide an adequate representation regarding a gene that is toxic to ***any*** bacteria or a method of producing an expression library that has the "one gene" that is toxic to ***any*** bacteria.

The specification description is directed to the method for constructing an expression library of bacteria (pg. 6, paragraph [0018] to pg. 9, paragraph [0027]). This method clearly does not provide an adequate representation regarding a method of making an expression library containing a gene that is toxic to bacteria. The specification examples are drawn to the method for constructing an expression library of *E. coli* and *B. subtilis* (pg. 17-20). The specification does not teach the method of a method of making an expression library containing a gene that is toxic to bacteria.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of the method for constructing an expression library of bacteria disclosed by the specification, the skilled artisan cannot envision the method of a method of making an expression library containing a gene that is toxic to bacteria. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30

USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the specification supports the method for constructing an expression library of bacteria. The specification does not teach the method of making an expression library containing a gene that is toxic to bacteria. Therefore, only the method for constructing an expression library of bacteria, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

7. Claims 1-4 and (new claim 8) are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the step of determining the gene in the first bacterium that would be toxic to the second bacterium. This step is essential in order to produce the expression library containing a gene that is toxic to bacteria.

Response to Arguments

8. Applicant's argument directed to the rejection under 35 U.S.C. 112, first paragraph (written description), for claims 1-4, and new claim 8 has been fully considered but they are not persuasive for the following reasons.

Applicant contends that the amendment claim 1 would overcome the rejection under 35 U.S.C. 112, first paragraph (written description) because "*Claim 1 has been amended to recite that the claimed method is for preparing a genomic expression library of a first bacterium which potentially contains a gene insert that encodes a product that is toxic to a second bacterium. The method comprises the steps of partially, digesting the genome of the first bacterium to provide genetic inserts, cloning and ligating the genetic inserts into a cloning vector, and directly transforming the ligation products into yeast.*" Thus the amended claim 1 has overcome the rejection under 35 U.S.C. 112, first paragraph (written description).

Applicant's arguments are not convincing since the amended claim 1 does not overcome the rejection under 35 U.S.C. 112, first paragraph (written description). The issues with regard to the written description rejection are 1) the specification disclosure does not sufficiently teach the method of making an expression library containing a gene that is toxic to bacteria because the claimed method requires prior knowledge that the "gene" in the first bacterium would be toxic to the second bacterium in order to isolate it, i.e. the instant claimed step (a) of claim 1; 2) the specification disclosure does not sufficiently teach the presently claimed method wherein "one toxic gene" is toxic to ***any*** bacterium; 3) the specification does not teach the method of making an expression library containing a gene that is toxic to bacteria. First, the addition of the term "potentially" would not overcome the issues with regard to the written description rejection, i.e.

1) the specification disclosure does not sufficiently teach the method of making an expression library containing a gene that is toxic to bacteria because the claimed method requires prior knowledge that the "gene" in the first bacterium would be toxic to the second bacterium in order to isolate it, i.e. the instant claimed step (a) of claim 1; 2) the specification disclosure does not sufficiently teach the presently claimed method wherein "one toxic gene" is toxic to ***any*** bacterium; 3) the specification does not teach the method of making an expression library containing a gene that is toxic to bacteria, for the term "potential" would encompassed that the method requires prior knowledge that the "gene" in the first bacterium would be toxic to the second bacterium, the expression library, i.e. the resulting product of the claimed method, would contain a gene that is toxic to bacteria, and that "one toxic gene" is toxic to ***any*** bacterium. Additionally, applicant has indicated that the instant specification, i.e. "particularly paragraphs 65-68 and figure 2, show support for the presently claimed method "*for preparing a genomic expression library of a first bacterium which potentially contains a gene insert that encodes a product that is toxic to a second bacterium*". It is the examiner position that the specification disclosure of paragraphs 65-68 and figure 2 is not support for the presently claimed method but rather described the method of analyzing an expression library, i.e. paragraph 65 (lines 1-4) discloses the steps of 1) determining the fraction of clones that contain the insert, i.e. the genetic inset of the bacterium, and 2) identifying the inserts that are stable in yeast, but not in *E. coli*. Thus the amendment of claim 1 does not overcome the rejection under 35 U.S.C. 112, first paragraph (written description), and the rejection is maintained.

9. Applicant's argument directed to the rejection under 35 U.S.C. 112, second paragraph (as being incomplete for omitting essential steps), for claims 1-4, and new claim 8 has been fully considered but they are not persuasive for the following reasons.

Applicant alleges that the amendment of claim 1 would overcome the rejection under 35 U.S.C. 112, second paragraph (as being incomplete for omitting essential steps) because "*In view of the amendment to claim 1, which now recites a library that "potentially" contains a gene that is toxic to a second bacterium, applicants submit that claim 1 recites all the essential steps of the claimed method.*" Thus the amendment of claim 1 would overcome the rejection under 35 U.S.C. 112, second paragraph (as being incomplete for omitting essential steps).

Applicant's arguments are not convincing since the amendment of claim 1 would not overcome the rejection under 35 U.S.C. 112, second paragraph (as being incomplete for omitting essential steps) because the addition of the term "potential" would not correct the incompleteness of the presently claimed method of claim 1. The presently claimed method is still incomplete in omitting the essential step of determining the gene in the first bacterium that would be toxic to the second bacterium. This step is essential in order to produce the expression library containing a gene that is toxic to bacteria. Thus the amendment of claim 1 would not overcome the rejection under 35 U.S.C. 112, second paragraph (as being incomplete for omitting essential steps), and the rejection is maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
October 29, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER